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EXAMINER	
ORWIG, KEVIN S	

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1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/587,420	DAVIS ET AL.	
	Examiner	Art Unit	
	Kevin S. Orwig	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/28/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1-23 are currently pending and are the subject of this Office Action. This is the first Office Action on the merits of the claims.

Information Disclosure Statement

References lined-through on the information disclosure statement(s) were not considered because they were not provided in English.

Claim Objections

Claim 4 is objected to because of the following informalities: "n" in line two of the claim should be "in".

Claim 10 is objected to because of the following informalities: the space in the term "D, L" should be deleted to more clearly convey that the D,L racemate is the intended member of the Markush group.

Claim Rejections - 35 USC § 112 (2nd Paragraph)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 4-17, and 19-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2, 4-17, and 19-23 are indefinite in the recitation of the commercial sources of the various components in claim 2 (e.g. Lubrizol, code 2405). Recitation of the commercial sources for chemical components is analogous to the recitation of a trademark or trade name since the exact composition (e.g. purity) in the chemical can vary from batch to batch and is not fixed immutably by the manufacturer. Thus, the recitation of the source of goods, and not merely the goods themselves raises the issue of what exactly is being claimed. Further, it is not clear whether the components, as claimed, were purchased from these sources or whether the bulk chemicals were purchased from the recited commercial source and solutions were subsequently made from these. For example, is the claim intending to exclude only a *solution* of 0.05% potassium iodide purchased from Fisher (wherein the pre-made solution was purchased from Fisher), or is a 0.05% solution *made from* solid potassium iodide that was purchased from Fisher also excluded? If the latter is the case, what type of potassium iodide sold by Fisher qualifies? A search of "potassium iodide" on the Fisher website as of Jan. 29, 2009 returned 148 results for various potassium iodide products, from various primary sources (e.g. Mallinckrodt Baker, Fisher Chemical, Acros Organics, etc.) of varying form and chemical purity. The ordinary artisan could not be expected to know which of these products, or features thereof, is intended to be excluded by the claim language. The commercial sources of the components recited in claim 2 should

be removed to allow an ordinary artisan to ascertain the scope of the invention, which is currently not possible.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7, 10, 13-18, and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over GALLEY (WO 91/11105; Published Aug. 8, 1991) in view of MARTIN (U.S. 5,652,274; Issued Jul. 29, 1997).

1. Galley discloses anti-microbial compositions containing iodide ions, an oxidoreductase enzyme, namely glucose oxidase (i.e. an oxidizing agent), and its corresponding oxidizable substrate, D-glucose (abstract). Galley teaches that iodide anions are included in the compositions in the form of salts, such as potassium iodide and sodium iodide (page 3, lines 17-21). The compositions of the invention are useful materials for skin preparations and wound dressings due to their antibacterial activity (page 11, elements b, g, and h). The compositions provide antibacterial activity through the action of the glucose oxidase enzyme on glucose, which generates hydrogen peroxide (H_2O_2) in the presence of water and oxygen (page 1, lines 16-21). Galley teaches that the compositions may be in the form of water-containing gels (page 8, 2nd paragraph, lines 8-13 and 20-22). It is noted that the instant specification defines a hydrated hydrogel to be an aqueous gel in hydrated form (paragraph [0025]). Thus, the water containing gels of Galley are hydrated hydrogels, as would be recognized by the ordinary artisan. The compositions also advantageously incorporate at least one buffering agent to minimize the fall of pH which may otherwise occur after activation of the concentrated composition (page 7, lines 22-26).

2. Thus, the only difference between the disclosure of Galley and instant claim 1 is the presence of a source of lactate ions in the dressing. However, the inclusion of lactate as a component of skin dressings was well-known in the art at the time of the

invention. For example, Martin discloses therapeutic wound healing compositions for protecting and resuscitating mammalian cells (abstract) and are suitable as pharmaceutical appliances and topical vehicles such as dressings, which include topical gel formulations (column 42, lines 17-28 and 40). These compositions comprise lactate ions, including sodium lactate and zinc lactate (column 30, line 62 to column 31, line 7), which are well a well-known buffering agents and antioxidants. Martin teaches that the antioxidant activity of lactate makes it beneficial in wound dressings due to its ability to reduce injury to mammalian cells or increase the resuscitation rate of mammalian cells (column 30, lines 58-61; column 31, lines 10-14).

3. In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to include a source of lactate ions in the dressings of Galley. One would have been motivated to do so in order to provide a dressing composition with improved ability to reduce injury to mammalian cells or increase the resuscitation rate of mammalian cells as taught by Martin. Further, both Galley and Martin are concerned with the same problem in the art, namely the treatment of wounds using topical dressing compositions. Therefore one would have been motivated to look to Martin and would have had a high expectation of success in combining the teachings of Martin with those of Galley to produce a wound dressing with improved wound treatment ability. Thus, claims 1, 2, 10, 14-17, 22, and 23 are rendered obvious over the combination of Galley and Martin.

4. Regarding claims 3, 13, and 21, Galley teaches that D-glucose is present most preferably in a weight concentration of at least 0.2% (page 4, line 27), and exemplifies

glucose in weight % ranges from 0.5-40%, depending on the type of composition produced (see Examples 32, 35, 40, 43, and 48). Additionally, Galley teaches that suitable glucose precursors may be used alone or along with glucose to advantageously support more sustained antimicrobial activity (page 4, lines 33-36). One of ordinary skill in the art would readily recognize from this teaching that the availability (i.e. the amount) of glucose correlates with the amount of hydrogen peroxide generated. Thus, the ordinary artisan would be motivated to optimize the amount of glucose in the dressing compositions depending on the particular application and intended length of time for its use. For instance, dressings for more serious or chronic wounds might require more glucose to achieve a longer period of hydrogen peroxide generation than those intended for minor wounds requiring less hydrogen peroxide. The artisan would initially be guided by the range of glucose taught by Galley. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to produce a dressing composition comprising from 2.5-20% glucose as suggested by Galley. Claims 3, 13, and 21 are rendered obvious over Galley and Martin.

5. Regarding claims 4 and 5, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the hydrogel material of Galley as either a layer (e.g. a sheet or film layer within a more structured patch system) or as a spreadable amorphous gel. It is well within the purview of the ordinary artisan to select the best means of application for a wound dressing composition depending on the particular wound to be treated. Galley teaches the compositions as gels (i.e. an amorphous form) (page 8, lines13 and 22; page 10, line 26), and teaches their use in

wound dressings comprising impregnated materials (page 11, element g), suggesting both of these configurations. Furthermore Martin teaches the use of the compositions in bandages to facilitate healing by delivering antioxidants (column 40, lines 47-57; column 42, lines 37-40), as well as teaching the compositions in conjunction with hydrogels (column 155, lines 46-49). Thus, the combination of Galley and Martin renders claims 4 and 5 obvious.

6. Regarding claims 6 and 7, Galley does not explicitly teach specific types of the hydrogel material. However, Galley teaches that the compositions are incorporated into conventional formulations suitable for topical application or pharmaceutical use (page 9, lines 4-12) and teaches formulations as gels (page 8, lines13 and 22; page 10, line 26). Martin also teaches compositions useful in hydrogels and teaches that such hydrogels generally comprise bioadhesive polymers such as polyacrylic acid. While the composition of typical hydrogels would have been known by the ordinary artisan, the combination of Galley and Martin provides sufficient guidance for the artisan to choose hydrophilic materials such as polyacrylates as the hydrogel material. The artisan would be motivated to do so in order to provide a bioadhesive hydrogel as taught by Martin. Thus, Galley and Martin render claims 6 and 7 obvious.

7. Regarding claim 18, Galley teaches that the compositions may be provided in the form of two or more physically separated phases in which the glucose oxidase is prevented from coming into contact with D-glucose until immediately prior to use. For example, the inventive compositions may take the form of two or more pastes or gels which maintain the glucose oxidase and D-glucose in separate phases until the two are

combined prior to use (page 8, lines 17-24). Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to formulate the dressing compositions of Galley as a first hydrogel layer comprising glucose (and lactate ions) and a second hydrogel layer comprising the oxidoreductase enzyme. One would have been motivated to do so to prevent the enzyme reaction from occurring prior to use by the consumer as taught by Galley. Claim 18 is obvious over the combination of Galley and Martin.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Claims 1, 6, 8, 9, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Galley in view of Martin as applied to claims 1-7, 10, 13-18, and 21-23 above, and further in view of MUNRO (U.S. 2002/0037270; Published Mar. 28, 2002).

8. The teachings of Galley and Martin are presented *supra*. Neither Galley nor Martin teaches the use of 2-acrylamido-2-methylpropane sulphonic acid (polyAMPS) as the hydrophilic polymer material in the compositions, and neither reference teaches the amount of the hydrophilic polymer in the hydrogels.

9. However, the use of polyAMPS in bioadhesive wound dressings was known in the art at the time of the invention. For example, Munro discloses wound dressings comprising hydrogel compositions having bioadhesive properties (paragraph [0001]). Munro teaches that the polymers used in the hydrogel may include water soluble polymers such as poly(2- acrylamido-2-methylpropane-sulphonic acid) or one of its salts and its copolymers (paragraph [0054]). Munro teaches that "...polymerising and crosslinking water soluble monomers in the presence of water soluble polymers, water and polyhydric alcohols produces hydrogel materials with enhance rheological and consequently adhesive properties" (paragraph [0053]). Furthermore, Munro teaches that AMPS is most preferably used as a monomer in the hydrogel compositions (paragraph [0032]). The skilled artisan would have been motivated to use water soluble polymers such as poly(2-acrylamido-2- methylpropane-sulphonic acid) or its salts since they were known as preferred components of hydrogels for wound dressings and because polyAMPS would have enhanced the rheological and adhesive properties of the dressing as taught by Munro. Munro also teaches that the hydrogels of the invention most preferably include from 25-70% by weight of the polymeric component (paragraph [0036]).

10. While the teachings of Galley and Martin would clearly guide the ordinary artisan to formulate the compositions as hydrogels, neither Galley nor Martin explicitly describes the particular species of materials useful in the invention to a significant degree. The most specific teaching of these two references is found in Martin, where polyacrylates are taught as useful to make bioadhesive hydrogels as discussed above. Since this is a very general teaching of a broad genus of polymers useful in hydrogels, the ordinary artisan would have looked to the literature for guidance regarding the particular species of polyacrylate materials useful in the invention.

11. Based on these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to select a polymeric material comprising polyAMPS, and to use the polymeric material at a level of at least 30% by weight of the gel per the teachings of Munro to provide a suitable hydrogel dressing with enhanced rheological and adhesive properties. Thus, claims 8, 9, and 19 are rendered obvious over the combination of Galley, Martin, and Munro.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention

as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Claims 1, 11, 12, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Galley in view of Martin as applied to claims 1-7, 10, 13-18, and 21-23 above, and further in view of BARROWS (U.S. 5,372,802; Published Dec. 13, 1994).

12. The teachings of Galley and Martin are presented *supra*. While both Galley and Martin teach the use of zinc compounds in the hydrogel compositions, these teachings alone do not provide sufficient motivation for an ordinary artisan to intentionally include a distinct source of zinc ions.

13. However, zinc salts have long been known to have a stabilizing effect on hydrogen peroxide. For instance, Barrows discloses gel compositions comprising hydrogen peroxide that is stabilized by various zinc salts, including zinc lactate (abstract; column 3, lines 13-27; claims 1 and 6). Thus, the skilled artisan would have been motivated to include a source of zinc ions in order to inhibit degradation of the reactive hydrogen peroxide generated by the glucose oxidase, per the teachings of Barrows. In doing so, the ordinary artisan would have had a high expectation of providing a dressing composition wherein the antibacterial effect of the hydrogen peroxide is increased since there higher levels of hydrogen peroxide in the dressing due to the stabilizing effect of the zinc ions. Furthermore, both Galley and Martin teach the use of zinc compounds, illustrating the compatibility of zinc ions with these compositions. It would have been *prima facie* obvious to one of ordinary skill in the art

at the time of the invention to select zinc lactate as the zinc source since it was taught by Barrows as a suitable zinc compound to stabilize hydrogen peroxide and since it is taught by Martin as a suitable source of lactate (column 31, line 6). Further, since the prior art provides motivation to include both zinc and lactate ions in the dressing compositions, it would have been obvious to the skilled artisan to select zinc lactate since it represents an efficient way to provide both of these components using a single reagent. Therefore claims 11, 12, and 20 are rendered obvious over Galley, Martin, and Barrows.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Claims 1-4, 6, 15-17, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over ABRAHAM (WO 97/02811; Published Jan. 30, 1997; 3rd foreign reference on IDS dated Jul. 28, 2006).

14. Abraham discloses a hydrogel patch comprising an electrolyte solution and an enzyme capable of metabolizing glucose into hydrogen peroxide, particularly glucose oxidase (abstract; page 18, line 21; page 19, lines 10-12). Abraham teaches that the gel-forming material is a hydrophilic polymer (page 18, lines 22-30). The patch also preferably comprises a buffer to maintain the pH of the patch, a biocide, and a humectant (abstract; page 2, line 15 to page 3, line 10). The buffer may be a lactate salt (page 21, lines 30-32).

15. The invention disclosed by Abraham is essentially a hydrogel patch designed to measure the amount of glucose entering the device based on the enzymatic reaction of glucose oxidase with glucose. The hydrogen peroxide product of this reaction is able to diffuse through the electrolyte solution in the hydrogel and generate a signal at an electrode to indicate the glucose level. Thus, Abraham teaches a patch (i.e. a dressing) comprising all the elements of instant claim 1 except for the requirement that the patch itself carry a supply of glucose. However, one of ordinary skill in the art would be motivated to add a supply of glucose to the patch to provide a positive control for calibration purposes. Given the intended use of Abraham's hydrogel patch, the ordinary artisan would recognize the importance of careful calibration of the patch, and would understand that a viable way to calibrate the signal from glucose degradation would be to prepare a series of such hydrogel patches containing various known amounts of glucose. Using the signals from such a series, the artisan would be able to calibrate the signal (i.e. with this calibration curve) and obtain an accurate reading from the electrode as a result. Thus, claims 1-4, 6, and 15-17 are rendered obvious over Abraham.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

U.S. Patent Application No. 10/044,715

Claims 1-23 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-23 of copending Application No. 10/044,715. The

conflicting claims are not patentably distinct from each other because the scope of the '715 claims is identical to that of the instant claims.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

U.S. Patent Application No. 10/512,440

Claims 1-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2, 5-7, 21, 22, 24, 25, and 30 of copending Application No. 10/512,440 in view of Martin. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the '440 claims renders obvious that of the instant claims. The difference between the two claim sets is that the instant claims recite a source of lactate

ions. As discussed *supra*, the addition of lactate ions is obvious per the teachings of Martin.

Claims 1-23 are directed to an invention not patentably distinct from claims 2, 5-7, 21, 22, 24, 25, and 30 of commonly assigned 10/512,440. Specifically, the addition of a source of lactate ions is obvious per the teachings of Martin as discussed *supra*.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 10/512,440, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

U.S. Patent Application No. 10/587,547

Claims 1-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of copending Application No. 10/587,547. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the '547 claims renders obvious that of the instant claims. The '547 claims teach each element of the instant claims, rendering the two claim sets obvious variants over one another.

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Conclusion

No claims are currently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin S. Orwig whose telephone number is (571)270-5869. The examiner can normally be reached Monday-Friday 7AM-4PM (with alternate Fridays off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached Monday-Friday 8:00 am-5:00 pm at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KSO

/David J Blanchard/
Primary Examiner, Art Unit 1643